K020518 MAR

MAR 7 2002

Applicant: Medela Inc., 1101 Corporate Drive, McHenry, IL 60050
Contact Person: Marcel Felber, Tel (815) 363 1166 ext. 423; Fax (815) 363 1246
marcel.felber@medelainc.com
510(k) Submission for Medela® Symphony® Breastpump

Medela Powered Breast Pump
Symphony®

1. Sponsor's Name, Address and Contact Person:

Sponsor:
Medela Inc.
1101, Corporate Drive
McHenry, IL 60050
Ph: (815) 363 1166 ext. 423
Fax: (815) 363 0460

Contact Person:
Marcel Felber
Vice President Quality Management

Correspondent:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 52 28
Fax: +41 41 769 51 01

Contact Person
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: October 31st, 2001

2. Name of Device:

Trade Name: **Medela® Symphony®** Powered Breast Pump
Common Name: Powered Breast Pump
Classification Name: Powered Breast Pump (Classified Class II, per 21 CFR section 884.5160).

3. Name of Predicate Device(s):

- Medela® Classic™ Breast Pump, by Medela Inc., K801862
- Egnell Elite Breast Pump, by Ameda Medizintechnik AG (Hollister Inc.), K950531

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4. Description of Device:

The Symphony Powered Breast Pump is intended to express the mother's milk of a lactating woman. The pumping can be performed on one breast or on both breasts at the same time. A DC motor is employed to drive both diaphragm pumps, one for each breast. These diaphragm pumps create the negative pressure (suction), required to extract the breast milk. Because the motor is controlled by a programmable microcontroller, the mother can potentially select from a number of pumping (suction) programs. The various pumping programs are stored on separate microchip cards, which the user inserts into the Breast Pump, prior to operating the device. The card is similar in size to a credit card.

The Symphony Powered Breast Pump employs a control knob, for the user to adjust the applied vacuum. The suction cycles (pump speed) are pre-programmed, either constant or variable. The breast pump is capable of providing vacuum levels from 0 to 250mm Hg, with cycling rates up to 130 cycles per minute. Configured with a typical **Symphony® Program**, the breast pump will provide a "Stimulation" mode of fast cycles along with an "Expression" mode of slower cycles.

All materials with milk contact or components with human breast contact are manufactured from materials that meet the appropriate FDA and international regulations concerning food contact and/or biocompatibility.

5. Intended Use of the Device:

The Symphony Powered Breast Pump is intended to express and collect the mother's milk from the breasts of a lactating woman, thus identical to the predicate devices.

6. Summary of Technological Characteristics:

The technology of the Symphony® powered breast pump is identical to the predicate devices and there are no technical differences which would raise new aspects regarding safety and effektiveness.

7. Conclusion:

Based upon the information presented above, it is concluded that the proposed Symphony Powered Breast Pump is safe and effective for the intended use, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2002

Medela, Inc.
% Mr. Mark Job
Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K020518
Trade/Device Name: Medela Symphony
Electrically Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: February 12, 2002
Received: February 19, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020518

Device Name: **Symphony**

Indications For Use:

The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020518

Over-the-Counter Use ✓